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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/933,115	08/20/2001	Paul B. Fisher	A34466 (070050.1618)	7088
21003	7590	11/28/2006	EXAMINER	
BAKER & BOTTS L.L.P. 30 ROCKEFELLER PLAZA 44TH FLOOR NEW YORK, NY 10112-4498			ANGELL, JON E	
			ART UNIT	PAPER NUMBER
			1635	

DATE MAILED: 11/28/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/933,115

Applicant(s)

FISHER, PAUL B.

Examiner

Jon Eric Angell

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 September 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 80 and 81 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 81 is/are allowed.
- 6) ☒ Claim(s) 80 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 20 August 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 9/11/2006 has been entered.

Applicant's arguments are addressed on a per section basis. The text of those sections of Title 35, U.S. Code not included in this Action can be found in a prior Office Action. Any rejections not reiterated in this action have been withdrawn as being obviated by the amendment of the claims and/or applicant's arguments.

Claims 80 and 81, the only claims currently pending, are examined herein.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 80 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that

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the inventor(s), at the time the application was filed, had possession of the claimed invention.

This is a new matter rejection.

37 CFR 1.118 (a) states that "No amendment shall introduce new matter into the disclosure of an application after the filing date of the application".

MPEP §2163.06 notes:

If new matter is added to the claims, the examiner should reject the claims under 35 U.S.C. 112, first paragraph - written description requirement. In re Rasmussen, 650 F.2d 1212, 211 USPQ 323 (CCPA 1981).

MPEP §2163.02 teaches that:

Whenever the issue arises, the fundamental factual inquiry is whether a claim defines an invention that is clearly conveyed to those skilled in the art at the time the application was filed...If a claim is amended to include subject matter, limitations, or terminology not present in the application as filed, involving a departure from, addition to, or deletion from the disclosure of the application as filed, the examiner should conclude that the claimed subject matter is not described in that application.

MPEP §2163.06 further notes:

When an amendment is filed in reply to an objection or rejection based on 35 U.S.C. 112, first paragraph, a study of the entire application is often necessary to determine whether or not "new matter" is involved. Applicant should therefore specifically point out the support for any amendments made to the disclosure. (Emphasis added).

Claim 80 is drawn to a method for treating a subject having pancreatic cancer comprising administering to the subject two nucleic acid sequences. Claim 80 has been amended to include the new limitation that the nucleic acid sequence of part (c) encodes a protein which "binds to an antibody directed toward the peptide fragment of SEQ ID NO: 2 having the sequence Pro-Ser-Gln-Glu-Asn-Glu-Met-Phe-Ser-Ile-Arg-Asp (SEQ ID NO: 5)..." Applicants have indicated that support for the new limitation can be found in paragraph 47.

It is noted that paragraph 47 (on pages 22-23) recites:

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[0047] MDA-7 may also be produced by yeast or bacterial expression systems. For example, bacterial expression may be achieved using plasmids such as pCEP4 (Invitrogen, San Diego, Calif.), pMAMneo (Clontech, Palo Alto, Calif.; see below), pcDNA3.1 (Invitrogen, San Diego, Calif.), etc.

Clearly, paragraph 47 does not provide support for the new limitation.

The specification was carefully reviewed to identify support for the indicated limitation.

It is noted that the closest support for the new limitation was found in paragraph 42 (on page 19) which recites:

[0042] The use of the term "increasing" does not presuppose that detectable levels of MDA-7 protein are constitutively present in the cell prior to treatment, such that the level may be "increased" from an undetectable or 0 level. An increase in MDA-7 protein may be evaluated indirectly by detecting the presence of and/or quantifying the amount of MDA-7 encoding mRNA or directly by detecting the presence of and/or quantifying the amount of MDA-7 protein. MDA-7 encoding mRNA may be detected, for example, by Northern blot or by reverse transcription-polymerase chain reaction ("RT-PCR") (e.g. using mda-7 specific primers such as ATGCTCTGTCCCTGCAGATA (SEQ ID NO:3) and CTCTGGATGCTGTGAAGAGT (SEQ ID NO:4) as described in Jiang et al., 1995, Oncogene 11:2477-2486. **MDA-7 protein may be detected by Western blot, for example using antibody directed against an MDA-7 specific peptide such as Pro-Ser-Gln-Glu-Asn-Glu-Met-Phe-Ser-Ile-Arg-Asp (SEQ ID NO:5; amino acid residues 153-164 of MDA-7 protein)**, also described in Jiang et al., 1995, Oncogene 11:2477-2486. In preferred embodiments, the amount of MDA-7 protein increases by a factor of at least 5, and more preferably by a factor of at least 10. (Emphasis added).

Paragraph 42 does not provide support for the new limitation because it does not contemplate the nucleic acid sequences encompassed by claim 80 part (c). Paragraph 42 discloses that MDA-7 protein may be detected using an antibody directed against an MDA-7 specific peptide, such as SEQ ID NO: 5. The instant claim encompass a method comprising administering a nucleic acid sequence that (1) specifically hybridizes to a nucleic acid comprising nucleotides 275-895 of SEQ ID NO: 1 under specific hybridization conditions, and

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(2) encodes a protein which binds to an antibody directed toward a peptide fragment having SEQ ID NO: 5 and which inhibits the proliferation of melanoma cells. Therefore, paragraph 42 does not provide proper support for using the genus of nucleic acid sequences of step (c) in a method of treating pancreatic cancer.

To the extent that the claimed compositions and/or methods are not described in the instant disclosure, the claim is also rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention, since a disclosure cannot teach one to make or use something that has not been described.

Response to Arguments

Applicant's arguments filed 9/11/06 have been fully considered.

Applicant's arguments, with respect to the rejection(s) of claim(s) 80 under 35 U.S.C. 112, first paragraph have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in because the application does not have proper support for the new limitation(s) for the reasons indicated herein.

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Applicant's arguments, with respect to the rejection of claims under 35 U.S.C. first paragraph (scope of enablement) have been fully considered and, in view of the amendment, are persuasive. The rejection has been withdrawn.

Allowable Subject Matter

Claim 81 is allowed.

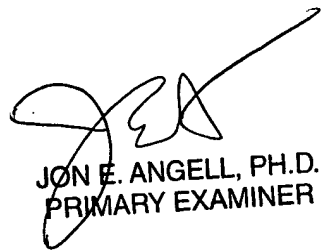
Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jon Eric Angell whose telephone number is 571-272-0756. The examiner can normally be reached on 9:00 a.m.- 5:00 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Douglas Schultz can be reached on 571-272-0763. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



JON E. ANGELL, PH.D.
PRIMARY EXAMINER